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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,549	08/18/2003	Richard Frederick Dechant		1961

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EXAMINER

GRAFFEO, MICHEL

ART UNIT PAPER NUMBER

1614

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/642,549

Applicant(s)

DECHANT, RICHARD FREDERICK

Examiner

Michel Graffeo

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: 2 pages of Revised Amendment Practice

DETAILED ACTION

Claim Status

Claim(s) have been filed on 18 August 2003, 8 November 2005 and 15 February 2006. The first claim filed on 18 August 2003 is claim 1. The single claim filed with a response on 8 November 2005 and the two claims filed on 15 February 2006 do not contain a statement of the status of that claim e.g., rejected, allowed or confirmed, withdrawn, objected to, or canceled as required by 37 CFR 1.121. To that extent, the claim filed on 8 November 2005 will be considered to be an original claim, claim 1, the claim filed on 8 November 2005 adds a limitation not present in the originally filed claim and is therefore claim 2. Claim 2 was filed again on 15 February 2006 along with a third claim, herein claim 3. Claim 1 was never canceled or withdrawn and will therefore be examined along with the claim filed on 8 November 2005, claim 2.

Pursuant to 37 CFR 1.121 amendments to the claims must include an identifier for each claim. See below for the applicable section of the rule as well as the attached sheet entitled "REVISED AMENDMENT PRACTICE: 37 CFR 1.121 CHANGED":

(c) Claims . Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) Claim listing. All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (e.g., Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) When claim text with markings is required. All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn—currently amended."

(3) When claim text in clean version is required. The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, i.e., without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, i.e., without any underlining.

(4) When claim text shall not be presented; canceling a claim.

(i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) Reinstatement of previously canceled claim. A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

Status of Action

Claims 1-2 are examined.

Applicant has added claim 3. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 3 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. The inventions of claims 1- 2 and claim 3 can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the composition can be used to deliver cosmetic ingredients (see US Patent Application No. 2003/0175328).

Applicant's arguments, see response, filed 15 February 2006, have been fully considered but are not persuasive. Any rejection not specifically stated in this Office Action has been withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2nd 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, because the specification and art, while enabling the treatment of visible tumors via direct application of the composition as well as treating precancerous cells using camphor and resorcinol or mixtures thereof and a chemotherapeutic agent sulfathiazole (as defined by the prior art but not the instant specification), does not reasonably provide enablement for the treatment of carcinomas and other cancers that are not be treated with via direct application, for example ovarian cancer. As a general matter, evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a reasonable correlation between the activity in question and the asserted utility. *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed.

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Cir. 1985); *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *Nelson v. Bowler*, 626 F.2d 853, 206 USPQ 881 (CCPA 1980). An applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of a compound or composition, arguments or reasoning, documentary evidence (e.g., articles in scientific journals), or any combination thereof. The applicant does not have to prove that a correlation exists between a particular activity and an asserted therapeutic use of a compound as a matter of statistical certainty, nor does he or she have to provide actual evidence of success in treating humans where such a utility is asserted. Instead, as the courts have repeatedly held, all that is required is a reasonable correlation between the activity and the asserted use. For example, if reasonably correlated to the particular therapeutic or pharmacological utility, data generated using in vitro assays, or from testing in an animal model or a combination thereof almost invariably will be sufficient to establish therapeutic or pharmacological utility for a compound, composition or process.

Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, because the scope of cancers treated and specifically the scope described by "any other susceptible forms of cancer" is not enabled since the treatment of cancer is generally an unpredictable art and the treatment of cancers which are defined only by functional language as here would require undue experimentation. For example, Gura (*Science*, 1997, 278:1041-1042) teaches that researchers face the problem of sifting through potential anticancer agents to find ones promising enough to make human clinical trials worthwhile and

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teach that since formal screening began in 1955, many thousands of drugs have shown activity in either cell or animal models but that only 39 have actually been shown to be useful for chemotherapy (p. 1041, see first and second para). Because of the known unpredictability of the art, in the absence of experimental evidence, no one skilled in the art would accept the assertion that the claimed composition could be predictably used as an anti-cancer agent for cancer therapeutic strategies as inferred by the claim and as contemplated by the specification. Further, the refractory nature of cancer to drugs is well known in the art. Jain (Sci. Am., 1994, 271:58-65) teaches that tumors resist penetration by drugs (p.58, col 1) and that scientists need to put expanded effort into uncovering the reasons why therapeutic agents that show encouraging promise in the laboratory often turn out to be ineffective in the treatment of common solid tumors (p. 65, col 3). Curti (Crit. Rev. in Oncology/Hematology, 1993, 14:29-39) teaches that solid tumors resist destruction by chemotherapy agents and that although strategies to overcome defense mechanisms of neoplastic cells have been developed and tested in a number of patients, success has been limited and further teaches that it is certainly possible that cancer cells possess many as yet undefined additional molecular mechanisms to defeat chemotherapy treatment strategies and if this is true, designing effective chemotherapeutic regimens for solid tumors may prove a daunting task (para bridging pages 29-30) and concludes that knowledge about the physical barriers to drug delivery in tumors is a work in progress (p. 36, col 2). It is clear that based on the state of the art, in the absence of experimental evidence, no one skilled in the art would accept the assertion that the claimed composition could be predictably used as an anti-

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cancer agent for cancer therapeutic strategies as inferred by the claim and as contemplated by the specification. In addition, anti-tumor agents must accomplish several tasks to be effective. They must be delivered into the circulation that supplies the tumor and interact at the proper site of action and must do so at a sufficient concentration and for a sufficient period of time. Also, the target cell must not have an alternate means of survival despite action at the proper site for the drug. In addition variables such as biological stability, half-life or clearance from the blood are important parameters in achieving successful therapy. The agent may be inactivated *in vivo* before producing a sufficient effect, for example, by degradation, immunological activation or due to an inherently short half life of the agent. In addition, the agent may not otherwise reach the target because of its inability to penetrate tissues or cells where its activity is to be exerted, may be absorbed by fluids, cells and tissues where the agent has no effect, circulation into the target area may be insufficient to carry the agent and a large enough local concentration may not be established. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict that the claimed invention would function as inferred and contemplated by the specification with a reasonable expectation of success. In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Applicant has not conveyed possession of the invention with reasonable clarity to one skilled in the art. The phrase "any other susceptible forms of cancer" is not described to the extent that one of ordinary skill in the art would readily appreciate the types of cancer treatable with the instant claim. The single species example provided is not sufficient to describe, absent any evidence of working examples or clearly described common mechanisms of action for example, the genus of types of cancer contemplated in claims 1-2 nor is it sufficient to provide predictable operability of the invention to one of ordinary skill in the art.

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the claimed invention. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those

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skilled in the art to any particular species); *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

Possession may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of the claimed invention.

Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. For example, a specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose or an applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole.

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application No 2003/0175328 to Shefer et al. in view of Camphor Monograph (Merck Index, 13th Edition, 2001 Monograph 01739), Resorcinol Monograph (Merck Index, 13th Edition, 2001 Monograph 08240) and Sulfathiazole Monograph (Merck Index, 13th Edition, 2001 Monograph 09031) and further in view of the Propylene glycol Monograph (Merck Index, 13th Edition, 2001 Monograph 07947).

Shefer et al. teach a method of topically treating (see Abstract) precancerous cells (see paragraph 24) comprising camphor and resorcinol or mixtures thereof (see paragraph 39) and a chemotherapeutic agent such as sulfathiazole (see paragraph 52) and a solubilizer such as propylene glycol (see paragraph 21) wherein the active agent is present in an amount of from 0.001% to about 80%.

Shefer et al. do not specifically teach the application of the composition via a cotton swab for 4-5 minutes.

Shefer et al. teach the application of the composition for a recommended treatment period (see paragraph 65) and also teach topical administration of the

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composition. Thus, one of skill in the art would have found it obvious to optimize the treatment duration and method of application. Additionally, Shefer et al. do not specifically recite a method of treating cancer, but yet teach a method of treating precancerous tissues. Nonetheless, the composition admittedly comprises a chemotherapeutic drug, sulfathiazole, which ultimately suggests its use as an anticancer composition.

The camphor monograph teaches that camphor is useful as a topical antiseptic agent (see Therapeutic Category).

The resorcinol monograph teaches that camphor is useful as a topical antiseptic agent (see Therapeutic Category).

The sulfathiazole monograph teaches that camphor is useful as an antibacterial agent (see Therapeutic Category).

The references do not expressly teach that the combination of the agents herein are useful in a composition. The references do not expressly teach that the amount of each agent: camphor, resorcinol and sulfathiazole are used in any particular amounts. Nonetheless, one of ordinary skill in the art would have appreciated the obviousness of the particular agent amounts through routine optimization. Further, the references do not expressly teach the employment of propylene glycol in the composition.

The propylene glycol monograph teaches that propylene glycol is useful as a solvent in pharmaceuticals (see Use section).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the agents herein into a composition because camphor,

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resorcinol and sulfathiazole are known in the art to be useful as an anti-microbial agent. One of ordinary skill in the art would have been motivated to combine the above references and as combined would teach the invention as claimed. In other words, Shefer et al. combined with the Merck monographs teach a method of treating cancer comprising the claimed ingredients. One of ordinary skill in the art would have been motivated to combine the references because combining agents which are known to be useful as antiseptics individually into a single composition useful for the very same purpose is *prima facie* obvious. See *In re Kerkhoven* 205 USPQ 1069. Since it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, the idea of combining camphor, resorcinol and sulfathiazole flows logically from their having been individually taught in the prior art. Further, one of ordinary skill in the art would have found it obvious to combine Shefer et al. with the Merck monographs because Shefer et al. teach a composition comprising each of the ingredients and the Merck monographs teach the therapeutic category common to each. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 15 February 2006 have been fully considered but they are not persuasive. As noted above, a written description must demonstrate that the Applicant had possession of the invention at the time of filing. A claim comprising

"other susceptible cancers" does not demonstrate that the Applicant had possession of the kinds of cancers which were susceptible.

Although as Applicant points out, Applicant's prior Application was filed prior to the earliest effective date of Shefer et al., but since the instant Application does not claim priority to the earlier Application, Applicant cannot rely on the earlier filing date.

In response to Applicant's point that the compounds react to form resorcincamphorein, the functionality of the compounds are a constant and to that end, that they are administered together under Shefer et al. or otherwise as described herein will function the same way. Therefore, Shefer et al. as combined with the monographs obviate the method as claimed.

Applicant's argument that the anecdotal evidence supports the instant claim is not persuasive. Applicant must establish a reasonable correlation between the activity in question and the asserted utility. An applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of a compound or composition, arguments or reasoning, documentary evidence (e.g., articles in scientific journals), or any combination thereof. For example, an Applicant can submit evidence that a specific cancer was or cancer cells were treated under a controlled and reproducible study.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

16 May 2006
MG

Ardin H. Marschel 5/27/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER

REVISED AMENDMENT PRACTICE: 37 CFR 1.121 CHANGED COMPLIANCE IS MANDATORY - Effective Date: July 30, 2003

All amendments filed on or after the effective date noted above must comply with revised 37 CFR 1.121. See Final Rule: **Changes To Implement Electronic Maintenance of Official Patent Application Records** (68 Fed. Reg. 38611 (June 30, 2003)), posted on the Office's website at: <http://www.uspto.gov/web/patents/ifw/> with related information. The amendment practice set forth in revised 37 CFR 1.121, and described below, replaces the voluntary revised amendment format available to applicants since February 2003. **NOTE: STRICT COMPLIANCE WITH THE REVISED 37 CFR 1.121 IS REQUIRED AS OF THE EFFECTIVE DATE (July 30, 2003).** The Office will notify applicants of amendments that are not accepted because they do not comply with revised 37 CFR 1.121 via a Notice of Non-Compliant Amendment. See MPEP 714.03 (Rev. 1, Feb. 2003). The non-compliant section(s) will have to be corrected and the entire corrected section(s) resubmitted within a set period.

Bold underlined italic font has been used below to highlight the major differences between the revised 37 CFR 1.121 and the voluntary revised amendment format that applicants could use since February, 2003.

Note: The amendment practice for reissues and reexamination proceedings, except for drawings, has not changed.

REVISED AMENDMENT PRACTICE

I. Begin each section of an amendment document on a separate sheet:

Each section of an amendment document (e.g., Specification Amendments, Claim Amendments, Drawing Amendments, and Remarks) must begin on a separate sheet. Starting each separate section on a new page will facilitate the process of separately indexing and scanning each section of an amendment document for placement in an image file wrapper.

II. Two versions of amended part(s) no longer required:

37 CFR 1.121 has been revised to **no longer require** two versions (a clean version and a marked up version) of each replacement paragraph or section, or amended claim. Note, however, the requirements for a clean version and a marked up version for **substitute specifications** under 37 CFR 1.125 have been retained.

A) Amendments to the claims:

Each amendment document that includes a change to an existing claim, cancellation of a claim or submission of a new claim, **must include a complete listing** of all claims in the application. After each claim number in the listing, the status must be indicated in a parenthetical expression, and **the text of each pending claim** (with markings to show **current** changes) must be presented. The claims in the listing will replace all prior claims in the application.

- (1) The current status of all of the claims in the application, including any previously canceled, not entered or withdrawn claims, must be given in a parenthetical expression following the claim number using only one of the following seven status identifiers: (original), (currently amended), (canceled), (withdrawn), (new), **(previously presented) and (not entered)**. The text of all pending claims, **including withdrawn claims**, must be submitted each time any claim is amended. Canceled **and not entered** claims must be indicated by only the claim number and status, without presenting the text of the claims.
- (2) The text of all claims **being currently amended** must be presented in the claim listing with markings to indicate the changes that have been made relative to the immediate prior version. The changes in any amended claim must be shown by underlining (for added matter) or strikethrough (for deleted matter) with 2 exceptions: (1) for **deletion of five characters or fewer, double brackets may be used (e.g., [[eroor]])**; and (2) if **strikethrough cannot be easily perceived (e.g., deletion of the number "4" or certain punctuation marks), double brackets must be used (e.g., [[4]])**. **As an alternative to using double brackets, however, extra portions of text may be included before and after text being deleted, all in strikethrough, followed by including and underlining the extra text with the desired change (e.g., ~~number 4~~ as number 14 as)**. An accompanying clean version is not required and should not be presented. Only claims of the status "currently amended," and "withdrawn" that are being amended, may include markings.
- (3) The text of pending claims **not being currently amended, including withdrawn claims**, must be presented in the claim listing in clean version, i.e., without any markings. Any claim text presented in clean version will constitute an assertion that it has not been changed relative to the immediate prior version except to omit markings that may have been present in the immediate prior version of the claims.

- (4) A claim being canceled must be listed in the claim listing with the status identifier “canceled”; the text of the claim must not be presented. Providing an instruction to cancel is optional.
- (5) Any claims added by amendment must be presented in the claim listing with the status identifier “(new)”; the text of the claim must not be underlined.
- (6) All of the claims in the claim listing must be presented in ascending numerical order. Consecutive canceled, or not entered, claims may be aggregated into one statement (e.g., Claims 1 – 5 (canceled)).

Example of listing of claims (use of the word “claim” before the claim number is optional):

Claims 1-5 (canceled)

Claim 6 (previously presented): A bucket with a handle.

Claim 7 (withdrawn): A handle comprising an elongated wire.

Claim 8 (withdrawn): The handle of claim 7 further comprising a plastic grip.

Claim 9 (currently amended): A bucket with a ~~green~~ blue handle.

Claim 10 (original): The bucket of claim 9 wherein the handle is made of wood.

Claim 11 (canceled)

Claim 12 (not entered)

Claim 13 (new): A bucket with plastic sides and bottom.

B) Amendments to the specification:

Amendments to the specification, including the abstract, must be made by presenting a replacement paragraph or section or abstract marked up to show changes made relative to the immediate prior version. An accompanying clean version is not required and should not be presented. Newly added paragraphs or sections, including a new abstract (instead of a replacement abstract), must not be underlined. A replacement or new abstract must be submitted on a separate sheet, 37 CFR 1.72. If a substitute specification is being submitted to incorporate extensive amendments, both a clean version (which will be entered) and a marked up version must be submitted as per 37 CFR 1.125.

The changes in any replacement paragraph or section, or substitute specification must be shown by underlining (for added matter) or strikethrough (for deleted matter) with 2 exceptions: (1) for deletion of five characters or fewer, double brackets may be used (e.g., [[error]]); and (2) if strikethrough cannot be easily perceived (e.g., deletion of the number “4” or certain punctuation marks), double brackets must be used (e.g., [[4]]). As an alternative to using double brackets, however, extra portions of text may be included before and after text being deleted, all in strikethrough, followed by including and underlining the extra text with the desired change (e.g., number 4 as number 14 as)

C) Amendments to drawing figures:

Drawing changes must be made by presenting replacement figures which incorporate the desired changes and which comply with 37 CFR 1.84. An explanation of the changes made must be presented either in the drawing amendments, or remarks, section of the amendment, and may be accompanied by a marked-up copy of one or more of the figures being amended, with annotations. Any replacement drawing sheet must be identified in the top margin as “Replacement Sheet” and include all of the figures appearing on the immediate prior version of the sheet, even though only one figure may be amended. Any marked-up (annotated) copy showing changes must be labeled “Annotated Marked-up Drawings” and accompany the replacement sheet in the amendment (e.g., as an appendix). The figure or figure number of the amended drawing(s) must **not** be labeled as “amended.” If the changes to the drawing figure(s) are not accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

Questions regarding the submission of amendments pursuant to the revised practice set forth in this flyer should be directed to: Elizabeth Dougherty or Gena Jones, Legal Advisors, or Joe Narcavage, Senior Special Projects Examiner, Office of Patent Legal Administration, by e-mail to patentpractice@uspto.gov or by phone at (703) 305-1616.